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No. 91-1957

IN THE
Supreme Court of the United States
OCTOBER TERM, 1992

CHEMICAL SPECIALTIES MANUFACTURERS ASSOCIATION,
Petitioner,
v.
STEVEN A. BOOK, *et al.*,
Respondents.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit

PETITIONER'S REPLY BRIEF

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TABLE OF CONTENTS

	Page
TABLE OF AUTHORITIES	ii
ARGUMENT	1
I. THE NATIONAL SIGNIFICANCE OF THE FEDERAL PREEMPTION ISSUE IN THIS CASE IS NOT DIMINISHED BECAUSE ONLY CALIFORNIA HAS ENACTED PROPOSITION 65	1
II. THE COURT OF APPEALS ERRED BY FAILING TO RECOGNIZE THAT PROPOSITION 65 WARNING REQUIREMENTS CONSTITUTE "LABELING" AND ARE AN OBSTACLE TO THE FIFRA LABELING PROGRAM	3
A. Written Warning Information Provided by the Manufacturer, Accompanying the Product, and Intended for the Pesticide Purchaser is Labeling Under FIFRA	3
B. Labeling Need Not Be Present During Product Use	5
C. FIFRA's Express Preemption Clause Does Not Preclude Implied Preemption Analysis	6
III. THE COURT OF APPEALS ALSO ERRED BY FAILING TO RECOGNIZE THAT PROPOSITION 65 WARNINGS CONSTITUTE LABELING WITHIN THE MEANING OF FHSA AND ARE AN OBSTACLE TO THE FHSA LABELING PROGRAM	7
A. Proposition 65 Warnings Are Implied "Directions for Use"	7
B. Proposition 65 and FHSA Warnings Are Not Identical	8
C. *Cipollone* Does Not Preclude Implied Preemption Analysis of FHSA	9
CONCLUSION	10

TABLE OF AUTHORITIES

CASES Page

American Meat Inst. v. Ball, 424 F. Supp. 758 (W.D. Mich. 1976) 4
Brown v. Hotel & Restaurant Employees & Bartenders Int'l Union, 468 U.S. 491 (1984) 6
Cipollone v. Liggett Group, Inc., 112 S. Ct. 2608 (1992) 1, 6, 9, 10
Gade v. National Solid Wastes Management Ass'n, 112 S. Ct. 2374 (1992) 6
Ingredient Communication Council, Inc. v. Lungren, 4 Cal. Rptr. 2d 216 (Cal. Ct. App. 1992) 5
Jones v. Rath Packing Co., 430 U.S. 519 (1977) 6-7
Kordel v. United States, 335 U.S. 345 (1948) 5
New York State Pesticide Coalition, Inc. v. Jorling, 874 F.2d 115 (2d Cir. 1989) 4, 6
Wisconsin Public Intervenor v. Mortier, 111 S. Ct. 2476 (1991) 7

CONSTITUTION

U.S. Const. art. VI, cl. 2 (Supremacy Clause) 6

STATUTES

Federal Cigarette Labeling and Advertising Act, 15 U.S.C. §§ 1331-1341 (1988) 6
Federal Hazardous Substances Act ("FHSA"), 15 U.S.C. §§ 1261-1277 (1988 & Supp. II 1990) ..... *passim*
FHSA § 2(n), 15 U.S.C. § 1261(n) (1988) 7, 8
FHSA § 2(p)(1), 15 U.S.C. § 1261(p)(1) (1988) 7, 8
FHSA § 18(b)(1)(A), 15 U.S.C. § 1261 note (b)(1)(A) (1988) 10
FHSA § 18(b)(3)(A), 15 U.S.C. § 1261 note (b)(3)(A) (1988) 10

TABLE OF AUTHORITIES—Continued

	Page
Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), 7 U.S.C. §§ 136-136y (1988 & Supp. II 1990)	*passim*
FIFRA § 2(p)(2), 7 U.S.C. § 136(p)(2) (1988)	3
FIFRA § 2(q)(1)(E), 7 U.S.C. § 136(q)(1)(E) (1988)	5
FIFRA § 24(b), 7 U.S.C. § 136v(b) (1988)	6, 7
Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65), Cal. Health & Safety Code §§ 25249.5-.13 (West Supp. 1992)	*passim*
REGULATIONS	
16 C.F.R. § 1000.7(a) (1992)	8
16 C.F.R. §§ 1061.1-.12 (1992)	10
49 Fed. Reg. 37,960 (Sept. 26, 1984)	4
52 Fed. Reg. 34,698 (Sept. 14, 1987)	7-8
Cal. Code Regs. tit. 22, § 12601(a) (1992)	9
Cal. Code Regs. tit. 22, § 12601(b)(4)(A), (B) (1992)	9
Cal. Code Regs. tit. 22, § 12601(b)(5) (1992)	3
Final Statement of Reasons (Oct. 6, 1988)	4
OTHER AUTHORITIES	
CPSC Advisory Op. No. 312 (Mar. 6, 1991)	8
Amicus Curiae Br. of States of California, Arizona, Indiana, Maryland, New Jersey and Washington Supporting Resp'ts, *Wisconsin Public Intervenor v. Mortier*, 111 S. Ct. 2476 (1991)	7
Letter from EPA Counsel James H. Curtin to Edward G. Weil (Aug. 7, 1990)	1-2

PETITIONER'S REPLY BRIEF

ARGUMENT

In their Opposition Brief, Respondents (hereinafter "the State") deny that California Proposition 65 represents a nationally significant threat to the viability of the federal cautionary labeling programs for consumer products under the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA") and the Federal Hazardous Substances Act ("FHSA"). The State argues that Proposition 65 is merely one state's law; disputes that the Ninth Circuit's holding that Proposition 65 warning requirements do not constitute requirements for "labeling" under FIFRA or FSHA directly conflicts with Supreme Court and Second Circuit precedents on the meaning of "labeling"; and contends that no implied preemption analysis of Proposition 65 is permissible in light of *Cipollone v. Liggett Group, Inc.*, 112 S. Ct. 2608 (1992), since FIFRA and FHSA contain express preemption provisions. For reasons given below, the State protests CSMA's petition too much with too little basis.

I. THE NATIONAL SIGNIFICANCE OF THE FEDERAL PREEMPTION ISSUE IN THIS CASE IS NOT DIMINISHED BECAUSE ONLY CALIFORNIA HAS ENACTED PROPOSITION 65.

The State tries to downplay the nationwide impact of its Proposition 65 warning requirements on the federal labeling of consumer pesticide and hazardous substance products by quoting EPA Administrator Reilly on the value of "providing information to the public," and by noting that as yet no other state has adopted such a law. Br. for Resp'ts in Opp. to Pet. for Writ of Cert. ("Resp't") at 8. The State's use of Mr. Reilly's letter on Proposition 65 is both misleading and troubling since the State knows full well that the letter "does not express the Agency's official position" on preemption under FIFRA. Letter from EPA Counsel James H. Curtin to

Edward G. Weil (Aug. 7, 1990), Ex. B to Weil Decl. (R. 41). Indeed, EPA counsel expressly instructed the State not to use Mr. Reilly's letter to support the inference which the State asks the Court to draw here.

Although no other states have passed Proposition 65-type legislation yet, California's enactment of this landmark law itself creates a nationally significant issue. With a resident population exceeding 29 million (representing almost 12 percent of the total U.S. population) California is by far the most populous state, and the dominant state market for consumer products. As such, California law unavoidably shapes marketing and labeling practices nationwide for consumer products like household pesticides and hazardous substances.[1]

Equally important, the State's opposition to CSMA's petition ignores altogether the deleterious impacts of Proposition 65 on the integrity of the federal labeling program caused by its point-of-sale warnings for cancer and reproductive effects, which conflict with the precautionary label warnings mandated by FIFRA and FHSA; on product liability exposure of national consumer pesticide and hazardous substances marketers, who disseminate such conflicting point-of-sale and product label warnings; and on consumers in California and elsewhere, who must choose which conflicting warnings to believe. *See* Pet. for Writ of Cert. ("Pet.") at 17-21. Through FIFRA's and FHSA's statutory preemption provisions, Congress sought to protect the integrity of the federal cautionary labeling program—the centerpiece of regulation under those Acts. The State urges the Court to overlook the formidable obstacle to achievement of this congressional goal simply because to date California is the only offending state. The Court should resist, however, and not condone even a

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[1] As indicated in the affidavit of Thayre Talcott, an industry labeling expert, once a large state like California requires precautionary warnings for a consumer product, manufacturers as a matter of commercial practicality will seek to modify their labels. Talcott Decl. ¶ 14 (R. 21).

single state's (much less California's) obstruction of the integrity of the federal labeling program.[2]

II. THE COURT OF APPEALS ERRED BY FAILING TO RECOGNIZE THAT PROPOSITION 65 WARNING REQUIREMENTS CONSTITUTE "LABELING" AND ARE AN OBSTACLE TO THE FIFRA LABELING PROGRAM.

Despite FIFRA's broad definition of labeling, 7 U.S.C. § 136(p)(2) (1988) ("written, printed, or graphic matter . . . accompanying the pesticide . . . at any time"), the State argues that Proposition 65 warning requirements escape FIFRA's reach by not requiring manufacturers to produce the actual retail sign; by permitting retail warnings "through shelf labeling, signs menus or a combination thereof"; and by terminating the warning obligation at the retail outlet. As the case precedents of this Court and the Second Circuit teach, however, these arguments are immaterial and do not change the character of Proposition 65 warning requirements as labeling under FIFRA.

A. Written Warning Information Provided by the Manufacturer, Accompanying the Product, and Intended for the Pesticide Purchaser Is Labeling Under FIFRA.

Proposition 65 regulations expressly require that a manufacturer of consumer pesticides (and each successive transferee) *"shall provide a warning* to any person to whom the product is sold or transferred unless the product is packaged or labeled with a clear and reasonable warning." Cal. Code Regs. tit. 22, § 12601(b)(5) (1992) (emphasis added). Furthermore, the very purpose of this requirement is *"to ensure that goods passing through a distribution chain are accompanied by warning materials*

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[2] The detrimental impact of Proposition 65 goes beyond FIFRA and FHSA and encompasses other federal health, safety and environmental laws. *See amicus curiae* briefs of the Chemical Manufacturers Association and the Committee for Uniform Regulation and Labeling submitted in support of Petitioner CSMA's certiorari petition.

or information" and "that the person who finally distributes the product to the consuming public will have knowledge of the need to warn, and will do so." Final Statement of Reasons (accompanying Cal. Code Regs. tit. 22, § 12601) at 30-31 (Oct. 6, 1988) (emphasis added). Regardless of whether the manufacturer must provide the actual point-of-sale warning sign, Proposition 65 mandates that the manufacturer distribute with its product the "warning materials or information," so that the required warning accompanies the product to the retailer, who thereby knows to generate a conspicuous display to the purchaser.

The warning information required of the manufacturer under Proposition 65 is labeling within the meaning of FIFRA because it is "designed to be read and followed by the end user" (i.e., the purchaser), *New York State Pesticide Coalition, Inc. v. Jorling*, 874 F.2d 115, 119 (2d Cir. 1989), and because "the primary intent of the federal labeling requirements is to regulate what producers say about their products." *American Meat Inst. v. Ball*, 424 F. Supp. 758, 762 (W.D. Mich. 1976). As EPA explains, " 'labeling' comprises those materials designed to accompany the product through the stream of commerce to the end user." *Jorling*, 874 F.2d at 120.

Whatever form the manufacturer's warning information may take, it satisfies FIFRA's broad definition of labeling. Indeed, as documented by former EPA Assistant Administrator for Pesticides and Toxic Substances Steven D. Jellinek, EPA has long considered to be labeling all such "[b]ulletins, leaflets, circulars, brochures, data sheets, flyers, or other written or graphic printed matter which is referred to on the label or which is to accompany the product." Jellinek Decl. ¶ 75 & Ex. G at 81 (R. 21); *see also* 49 Fed. Reg. 37,960, 37,972 (Sept. 26, 1984) (proposed definition).

Without citation the State asserts that a Proposition 65 point-of-sale warning does not accompany the product because "[i]t might be located immediately adjacent to the

product, or in some other location where it is likely to be seen by purchasers of the product." Resp't at 10. As the Court explained in *Kordel v. United States*, 335 U.S. 345, 350 (1948), however, the State's point is immaterial; "accompany" does not mean physical attachment—"It is the textual relationship that is significant." Furthermore, under Proposition 65 the point-of-sale sign must be "product-specific," that is, it must specifically identify the particular product to which it applies. *Ingredient Communication Council, Inc. v. Lungren*, 4 Cal. Rptr. 2d 216, 225 (Cal. Ct. App. 1992). By requiring this "textual" relationship between the warning and the product, Proposition 65 mandates that the warning be one that "accompan[ies] the pesticide" as that term is used in FIFRA. *See Kordel.*

B. Labeling Need Not Be Present During Product Use.

Finding no support in FIFRA's definition of labeling, the State invokes two particular misbranding and unlawful acts provisions of FIFRA to argue that point-of-sale warnings are not labeling because they need not "be available to the consumer *during use* of the product," and because FIFRA also regulates non-labeling claims. Resp't at 12.

FIFRA's definition of labeling, however, does not contain an exception for material which violates the misbranding prohibitions against labeling that fails to appear "in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use." 7 U.S.C. § 136(q)(1)(E) (1988). Misbranded labeling is still labeling. Further, FIFRA defines labeling to include materials accompanying the pesticide "at any time"—not just at the point of application; under Proposition 65 the warning information accompanies the product not merely "at any time," but all the way from the manufacturer through the channels of trade to the purchaser. Moreover, since the purchaser of consumer pesticides usually is also the end user, the Proposition 65 warning, like FIFRA labeling, "is

designed to be read and followed by the end user." *Jorling*, 874 F.2d at 119.

Finally, EPA's misbranding enforcement authority over pesticide claims which differ substantially from those approved at registration does not support the State's argument. Rather, it addresses unlawful claims made other than by written, printed or graphic means, such as salesmen's oral puffery or misleading broadcast advertising, as well as claims made by non-registrants such as distributors and retailers.

C. FIFRA's Express Preemption Clause Does Not Preclude Implied Preemption Analysis.

Citing the Court's recent decision in *Cipollone v. Liggett Group, Inc.*, 112 S. Ct. 2608 (1992), the State argues that CSMA's certiorari petition is governed solely by express preemption, and that no consideration can be given to implied (field or conflict) preemption. Moreover, the State proposes to obliterate all implied preemption analysis on the erroneous ground that the Federal Cigarette Labeling and Advertising Act's preemption clause has a broader sweep than does FIFRA § 24(b), 7 U.S.C. § 136v(b) (1988). This is not only incorrect given the comparable language in both preemption provisions, but also conveniently allows the State simply to conceal the deleterious effects that Proposition 65 warning requirements have on the integrity of the FIFRA labeling program. *See* Pet. at 17-21.

To the extent express preemption analysis does not confirm FIFRA's preemption of Proposition 65 warning requirements for consumer pesticides, *Cipollone* interposes no bar to traditional implied preemption analysis, especially "conflict" preemption which is governed "by direct operation" of the Supremacy Clause regardless of the presence or scope of a statutory preemption provision. *Brown v. Hotel & Restaurant Employees & Bartenders Int'l Union*, 468 U.S. 491, 501 (1984); *see also Gade v. National Solid Wastes Management Ass'n*, 112 S. Ct. 2374, 2388 (1992); *Jones v. Rath Packing Co.*, 430 U.S.

519 (1977) (holding that a state law regulating labeling of millers' flour is impliedly preempted due to direct conflict with federal law, even though the state law is not expressly preempted). Moreover, in *Wisconsin Public Intervenor v. Mortier*, 111 S. Ct. 2476, 2487 (1991), the Court confirmed that pesticide labeling "fall[s] within an area that FIFRA's 'program' pre-empts." Indeed, when appearing as *amicus curiae* in *Mortier*, the State itself acknowledged that "section 24(b), in precluding state regulation of labeling, evinces a congressional design to occupy the field of labeling regulation."[3] Thus, *Mortier* certainly invites field preemption analysis of FIFRA's prohibition against state labeling requirements.

III. THE COURT OF APPEALS ALSO ERRED BY FAILING TO RECOGNIZE THAT PROPOSITION 65 WARNINGS CONSTITUTE LABELING WITHIN THE MEANING OF FHSA AND ARE AN OBSTACLE TO THE FHSA LABELING PROGRAM.

A. Proposition 65 Warnings Are Implied "Directions for Use."

The State contends that the Proposition 65 warning requirement is not labeling under FHSA on grounds that the point-of-sale display is not "accompanying literature" under FHSA § 2(n), 15 U.S.C. § 1261(n) (1988), because it contains no "directions for use, written or otherwise." To the contrary, by raising the red flags of cancer and birth defects, Proposition 65 impliedly directs purchasers to minimize or avoid exposure. While the Proposition 65 warning admittedly is not a complete or sufficient direction for safe use, its very inadequacy as a use direction creates the sort of problem which Congress sought to prevent by defining FHSA labeling to include "accompanying literature" and then preempting non-identical state labeling requirements.[4]

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[3] *Amicus Curiae* Br. of States of California, Arizona, Indiana, Maryland, New Jersey and Washington Supporting Resp'ts at 9 n.4.

[4] As CPSC interprets § 2(p)(1) in its guidance about cautionary labeling against cancer hazards, 52 Fed. Reg. 34,698, 34,701 (Sept.

By defining "label" under FHSA § 2(n) to include "accompanying literature," Congress intended that point-of-sale information about the safe use of a product be *complete*, and *contain all* of the precautionary labeling required under FHSA § 2(p)(1). Proposition 65 point-of-sale signs omit this required precautionary information, fail to fully instruct purchasers through all the required label statements, and render the hazardous substances product misbranded under FHSA § 2(p)(1), 15 U.S.C. § 1261(p)(1) (1988).

Citing the Ninth Circuit's decision, the State asserts that the foregoing interpretation is "nonsensical," even though it is supported in an Advisory Opinion of the CPSC General Counsel. Authorized to provide "written advisory opinions interpreting the acts the Commission administers," 16 C.F.R. § 1000.7(a) (1992), the CPSC General Counsel determined that a Proposition 65 warning is an implied direction for use: "it conveys the information that, in using the product, steps should be taken to minimize or eliminate exposure," and thus constitutes labeling under FHSA § 2(n). Advisory Op. No. 312 at 3 (Mar. 6, 1991). Conversely, under the Ninth Circuit's interpretation, manufacturers and states alike are free to give partial, erroneous and misleading point-of-sale information about FHSA product safety since (not being a direction for use) that safety information would not constitute accompanying literature subject to misbranding.

B. Proposition 65 and FHSA Warnings Are Not Identical.

The State contends that because FHSA does not specify the precise label warnings, manufacturers can develop language that will satisfy Proposition 65 without violating

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14, 1987), a point-of-sale sign cannot simply warn about a principal hazard; it also must explain the factors which control the degree of risk and the precautions to be taken. Therefore, viewed (as it must) in the context of FHSA as a whole, "directions for use" include cautionary statements about product hazards, like the Proposition 65 warnings.

FHSA. This argument turns FHSA preemption on its head. By authorizing the states "to adopt requirements identical with the Federal requirements" for hazardous substances, Congress permitted the states to enforce FHSA through their own *identical* state laws—not to develop unique state requirements for when and how to warn about the same hazards regulated under FHSA.

Where FHSA's mandatory labeling requirements allow some discretion on wording and the states do not, the two are "non-identical"—even though they may be consistent. The State's interpretation of "identical" would open the door to fifty different state warnings for each hazard regulated under FHSA—all potentially at odds with one another but all arguably consistent with FHSA. Pet. at 24-27. Furthermore, Proposition 65 and FHSA warnings for consumer products are neither consistent nor identical. For FHSA-regulated products, Proposition 65 invariably requires use of the phrase "known to the State" [5] and the signal word "warning," whereas FSHA employs different cautionary language and signal words, depending on the particular product.

C. *Cipollone* Does Not Preclude Implied Preemption Analysis of FHSA.

The State's suggestion notwithstanding, *Cipollone* does not preclude implied preemption analysis simply because FHSA, like FIFRA, contains express preemption language. *See* discussion at 6-7, *supra*. Indeed, the direct conflict between Proposition 65 and FHSA cautionary labeling requirements is an essential part of this case

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[5] The State cannot disown the express regulatory requirement of Cal. Code Regs. tit. 22, § 12601(a) (1992) that the "message must clearly communicate that the chemical in question is *known to the state* to cause cancer, or birth defects or other reproductive harm." (Emphasis added); *see also id.* § 12601(b)(4)(A), (B) (the warning message for consumer products "must include" the language "known to the State of California to cause cancer").

which the court of appeals failed to appreciate, and which the State asks the Court to ignore. *See* Pet. at 24-26.

Further, the FHSA preemption provision ("no State or political subdivision of a State may establish or continue in effect a cautionary labeling requirement," 15 U.S.C. § 1261 note (b)(1)(A)) "sweeps broadly"—not narrowly, as the State implies. *See Cipollone*. The State also misconstrues the legislative history of the 1976 FHSA amendment about balancing minimum standards against uniform national requirements, which demonsrates the broad sweep of FHSA preemption. As amended in 1976, FHSA requires State governments to apply to CPSC for an exemption before imposing any non-identical precautionary labeling requirement, and requires the Commission to consider the "probability of other States . . . applying for an exemption . . . for a similar requirement, and *the need for a national, uniform requirement under [FHSA] for such substance*" before granting an exemption. 15 U.S.C. § 1261 note (b)(3)(A) (emphasis added); *see also* 16 C.F.R. §§ 1061.1-12 (1992). The State has upset this congressionally wrought balance by ignoring the FHSA exemption procedure while imposing different cautionary labeling on hazardous substances.

CONCLUSION

For the foregoing reasons, and those presented in CSMA's Petition, the Court should grant a writ of certiorari.

Respectfully submitted,

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